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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,773	03/16/2001	Frederick M. Ausubel	00786/380002	8780
21559	7590	12/18/2003	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			PARAS JR, PETER	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/809,773	Applicant(s) AUSUBEL ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-16, 29 and 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 17-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendment received on 9/15/03 has been entered. Claims 18, 20, and 26-27 have been amended. Claims 1-39 are pending. Claims 1-7, 17-28 and 30 are under current consideration.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7, 17-28 and 30, in Paper No. 9 is acknowledged.

Claims 8-16, 29 and 31-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Drawings

The color drawings are now compliant with 37 C.F.R. 1.84.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The previous rejection is maintained for the reasons of record advanced on page 3 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants have argued that the specification has defined the isolated

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nematode embraced by the claims to be a nematode that is purified and maintained in culture. Applicants also argue that an isolated pathogen is a microbial strain that has been cultured. Applicants further argue that Congress intended statutory subject matter to include anything under the sun that is made by man. See page 13 of the amendment.

In response, the Examiner maintains that the claimed nematode is a product of nature, which is non-statutory subject matter. It is further maintained that infection of the nematode by a pathogen does not alter its structure. Moreover, nematode pathogens exist in nature and are capable of infecting nematodes. Furthermore, the hand of man did not create the nematode as such are found in nature. Finally, Applicant's arguments regarding "isolated pathogen" are off-point because a pathogen, which has infected a nematode, can longer be considered as being isolated.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-7, 17-22, 24-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 4-6 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants argue virtually any nematode is useful in the invention. Applicants further argue nematodes are roundworms and are well known. See pages 14-15 of the amendment.

In response, the Examiner maintains the instant specification has failed to provide a description for nematodes, other than *C. elegans*, persistently infected by a pathogen as embraced by the claims. It is further maintained the instant specification has not disclosed which other nematodes are embraced by the claims. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art. It does not appear from the evidence of record that nematodes persistently infected with a pathogen are conventional in the art. Accordingly, it is maintained that applicant was not in possession of the necessary common features or attributes of the genus of nematodes persistently infected with pathogens.

Accordingly, the rejection is maintained for the reasons of record.

Claims 1-5, 17-20, 23-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 6-9 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants argue that the specification at page 4, lines 15-23 describes exemplary pathogens useful in the invention. See page 15 of the amendment.

In response, the Examiner asserts that pathogens other than bacteria have not been described by the instant specification. It is noted that all of the pathogens listed at page 4, lines 15-23 of the specification are all bacteria. Pathogens other than bacteria have not been contemplated by the instant specification. Accordingly, it is maintained that applicant was not in possession of the necessary common features or attributes of the genus of pathogens as embraced by the claims.

Accordingly, the previous rejection is maintained for the reasons of record.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 9-11 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants have amended claim 26 to now require a fragment of an antibody. See page 15 of the amendment.

In response, the Examiner maintains the instant specification has not described any fragment of any antibody. It is maintained that based upon the prior art variation among the species of antibodies because the art is replete with antibodies. The evidence of record has failed to provide any relationship between the structures of any antibody fragment and any antibody that would provide information about the structures of molecules within the genus. There is no evidence of record suggesting that any of the claimed antibody fragments can even function as antibodies. Accordingly, it is maintained that applicant was not in possession of the necessary common features or attributes of the genus of antibody fragments as embraced by the claims.

Accordingly, the previous rejection is maintained for the reasons of record.

Claims 1-7, 17-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *C. elegans* persistently infected with a bacterium and methods of using the same to screen for compounds, does not reasonably provide enablement for all other nematodes and pathogens embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection is maintained for the reasons of record advanced on pages 11-13 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants argue the instant specification teaches methods for generating isolated nematodes persistently infected with an isolated pathogen. Applicants further argue that the examples provided by the instant specification while exemplifying *C. elegans* and Salmonella could be extrapolated by a skilled artisan such that other nematodes and pathogens could be used when practicing the claimed invention. See pages 15-17 of the amendment.

In response, the Examiner maintains that the instant specification has failed to provide guidance for use of nematodes and pathogens, other than *C. elegans* and bacteria respectively, embraced by the claims. While the specification has contemplated that other nematodes and pathogens could be used in practicing the claimed invention, the specification has failed to recite which other nematodes and pathogens could be used. It is maintained that the specification has not provided any correlation between use of *C. elegans* and bacteria and use of any other nematode and pathogen in the claimed invention so that the skilled artisan could extrapolate use of a *C. elegans* and bacteria to use of other nematodes and other pathogens. A mere statement that other nematodes exist and could be used is not sufficient to enable the breadth of the claims as directed to any nematode persistently infected with any pathogen. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See *Genentech Inc. v. Novo Nordisk*

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A/S 42 USPQ2d 1001, 1997. It is maintained that the instant specification has not provided starting materials (nematodes and pathogens) for practicing the claimed invention, other than *C. elegans* and bacteria.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation "inhibition of pathogenicity" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The previous rejection is maintained for the reasons of record advanced on page 14 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants have argued claim 17 provides sufficient antecedent basis for the limitation "inhibition of pathogenicity" as it recites, "determining whether the test compound inhibits the pathogenicity of said pathogen". See page 18 of the amendment.

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In response, the Examiner asserts "inhibition of pathogenicity" and "inhibits the pathogenicity" do appear have the same meaning. Therefore, it is maintained "inhibition of pathogenicity" lacks antecedent basis.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan et al.

The previous rejection is maintained for the reasons of record advanced on pages 14-15 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants argue that Tan et al does not anticipate all of the instant claim limitations. In particular, Applicants argue that Tan has not taught nematodes persistently infected with a pathogen because Tan never explicitly states that *Pseudomonas* persistently infects a nematode. In addition, Applicants argue that because *Pseudomonas* may be found in the intestinal tract of *C. elegans* does not raise Tan to the level of an anticipatory reference. See pages 18-20 of the amendment.

In response, the Examiner maintains that Tan et al anticipates the claimed invention. The method used by Tan et al for infecting *C. elegans* appears to be the

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same as the method disclosed by the instant specification for obtaining a persistently infected nematode. Tan et al has taught seeding L4 stage *C. elegans* on culture plates containing *Pseudomonas*. It appears that the instant specification has provided essentially the same protocol for infecting nematodes. See pages 11 and 21 of the specification for example. Since the method of Tan et al and method disclosed in the instant specification appear to be the same, there appears to be sufficient evidence to believe that the method of Tan et al would have resulted in persistently infected nematodes. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01.

Accordingly, the previous rejection is maintained for the reasons of record.

Claims 1-5, 17-20, 23-26 and 30 rejected under 35 U.S.C. 102(b) as being anticipated by Ausubel et al. The previous rejection is maintained for the reasons of record advanced on pages 15-16 of the Office action mailed on 3/11/03.

Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive. Applicants argue that Ausubel et al does not anticipate all of the instant claim limitations. In particular, Applicants argue that Ausubel has not taught nematodes persistently infected with a pathogen because Ausubel never explicitly states that *Pseudomonas* persistently infects a nematode. In addition, Applicants argue that because *Pseudomonas* may be found in the intestinal tract of *C. elegans* does not raise Ausubel to the level of an anticipatory reference. See pages 18-20 of the amendment.

In response, the Examiner maintains that Ausubel et al anticipates the claimed invention. The method used by Ausubel et al for infecting *C. elegans* appears to be the same as the method disclosed by the instant specification for obtaining a persistently infected nematode. Ausubel et al has taught seeding L4 stage *C. elegans* on culture plates containing *Pseudomonas*. It appears that the instant specification has provided essentially the same protocol for infecting nematodes. See pages 11 and 21 of the specification for example. Since the method of Ausubel et al and method disclosed in the instant specification appear to be the same, there appears to be sufficient evidence to believe that the method of Ausubel et al would have resulted in persistently infected nematodes. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

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Accordingly, the previous rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time). The examiner is scheduled to move a new office, on 1/13/2004, having a new telephone number as follows: 571-272-0732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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PETER PARAS
PATENT EXAMINER

A handwritten signature in black ink, appearing to read "Peter Paras", written in a cursive style.